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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/944,234	10/06/1997	VINCENT BRYAN	A8038	1173

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EXAMINER

NGO, LIEN M

ART UNIT	PAPER NUMBER
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3727

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/944,234

Applicant(s)

KUNZLER ET AL.

Examiner

LIEN TM NGO

Art Unit

3727

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-125 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5-7 and 13-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24 & 37.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 3727

DETAILED ACTION

1. The request filed on 7/5/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/944,234 is acceptable and a CPA has been established. An action on the CPA follows.
2. Applicant's election without traverse of Species I, claims 1-3, 5-7 and 13-125, in Paper No. 39 is acknowledged.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the predetermined shape of an endoprosthesis (claims 18), the "concaval-convex shape" of an endoprosthesis (claim 24), the "surface contour in one of the adjacent vertebral bodies" (claims 24, 41, 47, 67, 82, 97, 114, 119, 120, 121), the "slot" (claims 29, 72, 86, 103), the "width of the insert" (claims 41, 49), the milling surface is "parallel to a receiving surface" (claims 49, 85, 102), the "nucleus puposus"(claim 51), the steps of the method claims 62-66, the " two predetermined surface contours"" (claims 77, 93, 110,), must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Art Unit: 3727

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-125 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example:

In claims 25, 41, 52, 67, 82, 97, 114, "at least one milling surface";

claims 29, 86, 103 "a slot";

claims 37, "a smooth surface";

claims 47, "at least one broad milling surface";

claim 48, "said drive...end plates"

claim 49, "said milling surface...by said device";

claim 51, "the width of the nucleus pulposus";

claim 53, "outwardly facing first and second milling surfaces";

claim 58, "said bearing surface is smooth";

claims 62-66, the steps of claimed methods;

claim 68, "first and second milling surfaces";

claims 36, 77, 93, 110 "at least two milling surfaces ... and end plate";

Art Unit: 3727

claims 37, 78, 82, "a smooth surface";
claim 98, "at least two milling surfaces";
claims 102, 119, "at least...vertebral bodies";
claim 120, "a broad milling surface";
claim 121, "at least one top milling surface".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36, 50, 53, 54, 77, 93-96, 98, 99 and 80, 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 80 and 81, "Said at least two milling surfaces" lack antecedent basis.

In claims 36, 50, 53, 54, 77, 93-96, 98 and 99, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte*

Art Unit: 3727

Steigewald, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 36, 50, 53, 54, 77, 93-96, 98 and 99 recite the broad recitation "at least one milling surface", and the claim also recite "at least two milling surfaces" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5-7 and 13-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645).

In regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in figs.1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant comprising head and bone drill comprising: a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm, as disclosed in col.17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means. (angle approximately 96 degrees which generally could be 90 degrees).

Art Unit: 3727

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In regard to claims 25-61 and 67-125, Scheicher device disclose all limitations as claimed.

In regard to method claims 62-66, Scheicher device ¹⁰³is capable to perform the steps as claimed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Lee Young, can be reached at (703)308-2572. The Group FAX number is (703) 305-3579.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-1148.

in

Lien Ngo

May 30, 2002

Lee Young
6/3/02
LEE YOUNG
SUPERVISORY PATENT EXAMINER
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